Technical Rejection Criteria for Study Data

Study Data Standards are required in clinical and nonclinical studies that start after December 17, 2016.[1] Technical rejection criteria is being added to the existing eCTD validation criteria to enforce the deadlines (see below). FDA will give the industry 30 days' notice on the eCTD website prior to the criteria becoming effective.

The FDA may **refuse to file (RTF) for NDAs and BLAs, or refuse to receive (RTR) for ANDAs**, an electronic submission that does not have study data in conformance to the required standards specified in the FDA Data Standards Catalog.

The standards apply to the following types of submissions to CDER and CBER:

- NDAs, ANDAs, BLAs, and all subsequent submissions to these types of applications, including amendments, supplements, and reports, even if the original submission was filed before the requirements went into effect.
- Commercial INDs (for products that are intended to be distributed commercially).

Deadlines: Sponsors whose studies started after **December 17, 2016** must use the data standards listed in the FDA Data Standards Catalog for NDAs, BLAs and ANDAs. For Commercial INDs, the requirement starts after **December 17, 2017.**

Although CDER and CBER can RTF or RTR submissions that do not conform to the required standards, we will implement a process to assess high-level study data standards conformance at the time the submission is submitted and validated. The criteria to be used to assess conformance are listed in the tables on page 2. If the submission fails these criteria, it will be rejected and the sponsor will be notified.

[1] Guidance to Industry: "Providing Regulatory Submissions In Electronic Format — Standardized Study Data

I M P O R T A N T

A Trial Summary dataset (ts.xpt) must be presented for each study in sections identified below *even if the study started prior to December 17, 2016*.

Study data validation **WILL APPLY** to the following eCTD sections:

- 4.2 Study Reports
- 5.3 Clinical Study Reports and Related Information

Study data validation **WILL NOT APPLY** to the following eCTD sections:

- 4.2.1 Pharmacology
- 4.2.2 Pharmacokinetics
- 4.2.3.3 Genotoxicity
- 4.2.3.5 Reproductive and Developmental Toxicity
- 4.2.3.6 Local Tolerance
- 4.2.3.7 Other Toxicity Studies
- 5.3.1.3 In Vitro – in Vivo correlation Study reports and related information
- 5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies
- 5.3.2 Reports of studies pertinent to pharmacokinetics using human biomaterials
- 5.3.3.5 Population PK study reports and related information[2]
- 5.3.5.3 Reports of Analyses of Data from More than One Study
- 5.3.5.4 Other Study Reports and Related Information
- 5.3.6 Reports of Postmarketing Experience

[2] PK/PD modeling and simulation study reports can be placed under this section, under Module 5.3.3.5.

eCTD Technical Rejection Criteria for Study Data

Number:	1734
Group:	General
Description:	A Trial Summary (TS) dataset must be present for each study in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4 and in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	TBD
Problem:	You have not submitted a Trial Summary (TS) dataset for each study in Module 4, section 4.2 or in Module 5, section 5.3
Corrective Action:	Resubmit, including a Trial Summary for each study in Module 4, section 4.2 and Module 5, section 5.3
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Standardized Study; Study Data Technical Conformance Guide.
Number:	1735
Group:	STF
Description:	The correct STF file-tags must be used for all standardized datasets in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4 and in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	TBD
Problem:	You have submitted XPT files without correct file tag. Valid file tags are: data-tabulation-dataset-sdtm data-tabulation-dataset-send analysis-dataset-adam
Corrective Action:	Resubmit using one of the valid file tags for all submitted datasets
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Standardized Study; Study Data Technical Conformance Guide.

Number:	1736
Group:	General
Description:	DM dataset and define.xml must be submitted in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4. DM dataset, ADSL dataset, define.xml must be submitted in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	TBD
Problem:	You have not submitted Demographic dataset (DM) and define.xml for each study in Module 4, section 4.2. You have not submitted Demographic dataset (DM), Subject level analysis dataset (ADSL), and define.xml for each study in Module 5, section 5.3
Corrective Action:	Resubmit the submission with the Demographic dataset (DM) and define.xml for each study in Module 4, section 4.2. Resubmit including Demographic data, Subject level analysis dataset, and define.xml for each study in Module 5, section 5.3
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Standardized Study; Study Data Technical Conformance Guide.

Number:	1737
Group:	General
Description:	For each study in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4 and in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2, no more than one dataset of the same name should be submitted as new
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	TBD
Problem:	You have submitted more than one dataset of the same type as new for a study
Corrective Action:	Corrective action may be necessary. In future submissions, ensure that only one dataset of each type is marked as new
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Standardized Study; Study Data Technical Conformance Guide.